

**Important Safety Information on the Distribution of a New Presentation of SPIKEVAX (elasomeran) COVID-19 Vaccine (0.10 mg/mL in 2.5 mL multidose vial) with English-only Vial and Carton Labels**



2022/06/06

**Audience**

Healthcare professionals including infectious disease physicians, pharmacists, family physicians, public health officials, nurses and nurse practitioners.

**Key messages**

- **On June 01, 2022, Health Canada authorized a NEW PRESENTATION of SPIKEVAX (elasomeran) with a concentration of 0.10 mg/mL in a 2.5 mL multidose vial with a ROYAL BLUE CAP (DIN 02527685).**
- **The original presentation of SPIKEVAX/COVID-19 Vaccine Moderna, 0.20 mg/mL in a 5 mL multidose vial with a red cap (DIN 02510014), has been available on the market since December 23, 2020 and continues to be available.**
- **The volume (mL) required for primary series and booster dosing will be different depending on which presentation of the vaccine is being administered. Careful attention should be paid to the vial and carton label, vial cap colour and corresponding dose volumes (see Tables 1 and 2 in the Information for healthcare professionals section).**
- **In order to provide rapid access to the new presentation of SPIKEVAX (0.10 mg/mL, 2.5 mL multidose vial), Moderna will distribute product vials and cartons with English only labels, for a period of time.**
- **Healthcare professionals are advised that:**
  - **Important Canadian-specific information is absent from the vial and carton labels (see the Information for healthcare professionals section).**
  - **The Canadian-specific labelling information, including the SPIKEVAX Product Monograph and training materials, can be accessed at [www.modernacovid19global.com/ca](http://www.modernacovid19global.com/ca), or by scanning the QR code on the English-only vial and carton labels. This information is also available on the federal government's [covid-vaccine.canada.ca](http://covid-vaccine.canada.ca) website. The SPIKEVAX Canadian Product Monograph in French and English is also available on Health Canada's [Drug Product Database](#).**
  - **Moderna will develop Canadian-specific vial and carton labels for the new presentation of SPIKEVAX (0.10 mg/mL, 2.5 mL multidose vial) and make them available on the [www.modernacovid19global.com/ca](http://www.modernacovid19global.com/ca) website at a future date.**

### **What is the issue?**

A new presentation of SPIKEVAX (elasomeran) with a concentration of 0.10 mg/mL in a 2.5 mL multidose vial was authorized on June 01, 2022. In order to provide rapid access to the new presentation of SPIKEVAX (0.10 mg/mL, 2.5 mL multidose vial), Moderna will distribute vaccine product with English-only carton and vial labels for a period of time. As a result, important Canadian-specific information is absent from these labels (see the Information for healthcare professionals section).

### **Products affected**

SPIKEVAX (elasomeran) (0.10 mg/mL), dispersion for intramuscular injection, multidose vial (2.5 mL), royal blue vial cap.  
DIN: 02527685

Manufacturer: ModernaTx, Inc.

Canadian Importer and Distributor: Innomar Strategies

### **Background information**

SPIKEVAX (elasomeran mRNA vaccine) is indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 6 years of age and older.

Given the public health emergency resulting from the current pandemic, Health Canada has authorized the importation, sale, and advertising of this new presentation of SPIKEVAX (0.10 mg/mL, 2.5 mL multidose vial) with vial and carton labels that are in English-only for the global distribution of the vaccine.

SPIKEVAX (0.10 mg/mL, 2.5 mL multidose vial) with English-only labels is the same as the Health Canada authorized SPIKEVAX in all aspects (i.e., formulation, strength, route of administration) and should be used in Canada for the same indication and per the same vaccination schedule. The Canadian Product Monograph for SPIKEVAX, which is approved by Health Canada and available in French and English, should be used for complete product information.

### **Information for healthcare professionals**

Healthcare professionals are advised that:

- On June 01, 2022, Health Canada authorized a new presentation of SPIKEVAX (0.10 mg/mL, 2.5 mL multidose vial).
- The original presentation of SPIKEVAX (0.20 mg/mL, 5 mL multidose vial) continues to be available. Please refer to the Health Product Risk Communication issued on [November 10, 2021](#) for more information.
- There are now 2 presentations of SPIKEVAX available in Canada. Both presentations are labelled with English-only vial and carton labels.
- The new presentation of SPIKEVAX (0.10 mg/mL, 2.5 mL multidose vial) is not intended for preparation of the 100 mcg dose.
- The volume (mL) required for primary series and booster dosing will be different depending on which presentation of the vaccine is being administered. Careful

attention should be paid to the vial and carton label, vial cap colour and corresponding dose volumes.

**Table 1. SPIKEVAX Presentations with English-Only Labels**

<b>SPIKEVAX Presentation</b>	<b>Vial Cap Colour</b>	<b>Volume in vial</b>	<b>Number of 0.5 mL doses</b>	<b>Number of 0.25 mL doses</b>
0.20 mg/mL (original) DIN 02510014	Red	5 mL	10	20*
0.10 mg/mL (new) DIN 02527685	Royal blue	2.5 mL	5	N/A

\*Do not puncture the 5 mL vial more than 20 times

**Table 2. SPIKEVAX Dosage Recommendations**

<b>Age Range</b>	<b>Vaccination</b>	<b>Dose</b>	<b>SPIKEVAX Presentation</b>	<b>Vial Cap Colour</b>	<b>Dose Volume</b>
18 years of age or older	Primary Series	100 mcg*	0.20 mg/mL	Red	0.5 mL
	Booster Dose	50 mcg	0.20 mg/mL	Red	0.25 mL
			0.10 mg/mL	Royal blue	0.5 mL
12 to 17 years of age	Primary Series	100 mcg*	0.20 mg/mL	Red	0.5 mL
6 to 11 years of age	Primary Series	50 mcg	0.20 mg/mL	Red	0.25 mL
			0.10 mg/mL	Royal blue	0.5 mL

\*The new 0.10 mg/mL presentation (2.5 mL multidose vial) is not intended for preparation of the 100 mcg dose.

- The approved SPIKEVAX Canadian Product Monograph, which is available in French and English on Health Canada’s [Drug Product Database](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/database.html), the federal government’s [covid-vaccine.canada.ca](https://www.covid-vaccine.canada.ca) website or at [www.modernacovid19global.com/ca](https://www.modernacovid19global.com/ca), should be used for complete product information.
- The following important Canadian-specific information is absent from the vial and carton labels:
  - Drug Identification Number (DIN)
  - name and address of the Canadian DIN holder
  - name and address of the Canadian importer and distributor
  - all corresponding text in French
- The Canadian-specific information can be accessed at [www.modernacovid19global.com/ca](https://www.modernacovid19global.com/ca), or by scanning the QR code on the

SPIKEVAX vial or carton labels. This information is also available on the federal government's [covid-vaccine.canada.ca](https://www.covid-vaccine.canada.ca) website.

### **Action taken by Health Canada**

Health Canada is permitting the use of an English-only label for a limited period. Health Canada has imposed terms and conditions requiring Moderna to provide vaccine supplies with Canadian-specific labels as soon as possible. Health Canada has made full labelling information available in French and English on the federal government's [covid-vaccine.canada.ca](https://www.covid-vaccine.canada.ca) website.

Health Canada is communicating this important safety information to healthcare professionals and Canadians via the [Recalls and Safety Alerts Database](#) on the Healthy Canadians Web Site. This communication update will be further distributed through the MedEffect™ e-Notice email notification system, as well as through social media channels, including LinkedIn and Twitter.

### **Report health or safety concerns**

Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any serious or unexpected side effects in patients receiving SPIKEVAX should be reported to your local Health Unit or Moderna.

#### **Moderna Biopharma Canada Corporation**

c/o SE Corporate Services Ltd., Suite 1700,  
Park Place, 666 Burrard Street,  
Vancouver, BC V6C 2X8

**Telephone: 1-866-663-3762**

**Fax: 1-866-599-1342**

**To correct your mailing address or fax number, contact Moderna Biopharma Canada Corporation at 1-866-MODERNA (1-866-663-3762).**

If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html>) and send it to your local Health Unit.

For other health product inquiries related to this communication, contact Health Canada at:

Biologic and Radiopharmaceutical Drugs Directorate  
E-mail: [brdd.dgo.enquiries@hc-sc.gc.ca](mailto:brdd.dgo.enquiries@hc-sc.gc.ca)

### **Original signed by**

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ModernaTX, Inc.

**Appendix A – Vial and carton labels for SPIKEVAX (elasomeran)  
0.10 mg/mL (DIN 02527685) with English-only labelling**

**SPIKEVAX Vial Label (0.10 mg/mL)**

Read the package leaflet before use.

703759

Discard Time: \_\_\_\_\_

**spikevax™ 0.10 mg/mL**

dispersion for injection  
COVID-19 mRNA Vaccine  
(nucleoside modified)  
elasomeran

**IM**

**Multidose vial  
2.5 mL**

Scan for package leaflet or visit  
[www.ModernaCovid19Global.com](http://www.ModernaCovid19Global.com)  
Moderna Biotech Spain S.L.

LOT  
EXP

Read the package leaflet before use.  
[QR CODE]  
Discard Time: \_\_\_\_\_

Scan for package leaflet or visit  
[www.ModernaCovid19Global.com](http://www.ModernaCovid19Global.com)  
Moderna Biotech Spain S.L.

**spikevax™  
0.10 mg/mL**

dispersion for injection  
COVID-19 mRNA Vaccine  
(nucleoside modified)  
elasomeran

**IM**

**Multidose vial  
2.5 mL**

LOT  
EXP

## SPIKEVAX Carton Label (0.10 mg/mL)



<p>Moderna spikevax™ dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) elasomeran Intramuscular Use</p>	<p><b>0.10 mg/mL</b></p> <p><b>10 multidose vials (each vial contains 2.5 mL)</b></p>
<p><i>Black box contains:</i> PC EXP LOT</p> <p>Moderna™ Moderna Biotech Spain, S.L.</p>	<p>Each multidose vial contains 2.5 mL. Excipients: Lipid SM-102, cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG), trometamol, trometamol hydrochloride, acetic acid, sodium acetate trihydrate, sucrose,</p>

Principe de Vergara 132  
Madrid 28002, Spain

water for injections.

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Store frozen at -50°C to -15°C. Read the package leaflet for the shelf life after first opening and for additional storage information.

Keep the vial in the outer carton to protect from light.

Keep out of sight and reach of children.

Dispose of in accordance with local requirements.

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Read the package leaflet before use.

Scan here for package leaflet or visit [www.ModernaCOVID-19Global.com](http://www.ModernaCOVID-19Global.com)

